

REMARKS

Status of Claims

Claims 1, 88, 91-95, 97-106, 118-120, 130-136, 138-141, 143-158, and 160-164 are pending.

Claims 130-136, 143-144 and 146-157 are withdrawn from consideration.

Claims 95, 141, and 158 are allowed.

Claims 1, 88, 91-94, 97-106, 118-120, 138-140, 142, 145, and 160-164 stand rejected.

Claims 1, 93, 97, 101, 130, 138, 144, 148, 149, 157, and 161 are amended herein.

No new matter is introduced.

Support for Amendments

Consistent with the Examiner's suggestion, claim 1 is amended to specify that the device is "for sampling and recovering a target." Support is found throughout the application as filed, including page 2, lines 15-17 and 20-35. Claims 93, 97, 101, 130, 138, 144, 148, 149, 157, and 161 are amended to remove the term collagen. No new matter is introduced by these amendments.

Interview Summary

Applicants thank the Examiner for the courtesies extended to Applicant's representatives during the March 15, 2010 interview at the USPTO. Jonathan Ball and Michael Willis of King & Spalding, LLP and Jesper Aamand, Janni Pedersen, and Marielle Dejligbjerg of Høiberg A/S were present on behalf of the Applicant. The Kelly reference was discussed during the interview and it was explained that the abstract and text of that reference unambiguously identify the swab material as "a polyester foam swab." The D'Alessio reference was also discussed and it was explained that those swabs are made of polyurethane, not gelatin, and are for applying liquid compositions to target sites on a patient's body -- a very different problem than sampling and recovering a target. Likewise, the Choi reference relates to gelatine-based sponges for use as wound dressings and does not teach or suggest the advantages of gelatine for sampling and recovering a target.

Claim Rejections

§ 103(a) -- D'Alessio & Choi

Claims 1 and 88 stand rejected under 35 U.S.C. §103(a) as being unpatentable over D'Alessio in view of Choi. The Examiner contends that D'Alessio discloses all of the features of claim 1, except the gelatine-based sponge of the swab.

Applicants respectfully traverse on the grounds that the applicator of D'Alessio is formed of polyurethane -- a material having well-documented limitations relating to surface interactions with biological molecules -- and therefore one skilled in the art, seeking to make a device for "sampling and recovering a target," would not have looked to D'Alessio's applicator. Choi likewise provides no motivation to utilize gelatine in a device for "sampling and recovering a target" because Choi relates to leave-in wound dressing and fails to recognize any potential for gelatine sponges high recovery of a target from a surface or medium. These references are discussed in more detail below.

D'Alessio relates to a disposable applicator which is said to be useful for applying liquid compositions to target sites (abstract; col. 1, lines 6-9; col. 3, lines 46-53 and 56-60; col. 4, lines 1-4 and 8-10). D'Alessio's applicator requires two swabs: an applicator swab and a drying swab (abstract, col. 3, lines 63-64; col. 4, lines 1-7 and 61-64). The liquid to be applied is contained within the applicator body in a frangible ampoule (col. 4, lines 57-60). Thus, D'Alessio is directed to applying liquid compositions to target sites on a patient's body by use of a device optimized for delivery of therapeutic liquids to biological tissue (col. 3, lines 46-53). There is no teaching in D'Alessio of alternate uses, such as collecting and recovering a target from a surface.

Indeed, not all materials are suited for the purpose of collecting sufficient amount of target without compromising viability and subsequent recovery of the target. Polyurethanes represent a vast class of materials and many polyurethanes have properties that would counsel against their use for sampling and recovering biologically interesting targets, including undesirable surface-target interactions. For example, the literature suggests that proteins can be denatured on polyurethane surfaces (Vermette et al., Biomedical Applications of Polyurethanes, Landes Bioscience, chapter 7.2, page 176) and this property would not recommend use to sample and recovery biological targets since poor recovery and unreliable results might be expected. As

the use made by D'Alessio is for application to a patient's body rather than sampling and recovery, there is no reason to believe that the applicator taught by D'Alessio would have the requisite properties required by the instant claims.

In contrast to the polyurethane swabs as taught by D'Alessio, the present inventors have found that gelatine-based swabs of the present invention achieve a surprisingly high recovery of collected target. Without being bound by theory, Applicants believe that an advantageous interaction occurs between the target (for example, cells) and the gelatine-based sponge of the swab of the instant invention. The advantageous interaction may prevent denaturation and result in higher recovery in the collection of the target and release to a transfer medium.

Choi does nothing to rectify the deficiencies of D'Alessio. Choi is directed to gelatine-based sponges for use as wound dressings. Choi's sponges are applied at the site of the wound and fixed in place with an elastic band. (See page 68, Sec. 2.4). The fact that a sponge is useful for wound healing, and is utilized as a leave-in dressing, says nothing about its ability to collect a target and recover the target in a transfer medium.

Therefore, in view of the fact that polyurethanes as taught by D'Alessio do not have the correct properties to be used in a single-use device for sampling and recovering as required in claim 1, and Choi fails to provide any teachings to remedy the deficiencies of D'Alessio, Applicants respectfully submit that it would not be obvious to combine D'Alessio with Choi to arrive at the claimed invention according to claim 1. Applicants respectfully request withdrawal of the rejection.

§ 103(a) -- Kelly & Choi

The Office Action rejects claims 91-95, 97-99, 101, 103, 105, 106, 118-120, 138-140, 161, 163, and 164 under 35 U.S.C. § 103(a) over Kelly in view of Choi. Applicants traverse.

The Kelly reference does not teach or suggest, expressly or inherently, the use of gelatine in a swab. In fact, Kelly specifically refers to a "polyester foam swab" and makes no reference whatever to gelatine as an ingredient in the swab. The "Summary" section of Kelly states that a "polyester foam swab was shown to have no advantage over the standard cotton wool variety," (p. 81, left column, lines 10-12) and the "Material and Methods" section likewise refers to "wooden-handled Gelfoam swabs* made from polyester foam." (p. 82, left column, lines 23-25).

Applicants submit that is improper for the Examiner to speculate that the material may have been gelatin when the Kelly reference states quite clearly that is not.

The Examiner points to a trademark registration in the name of the UPJOHN Company for Gelfoam specifying that the subject goods are “sterile surgical sponges made from specially treated gelatin” to contend that the material of Kelly is inherently gelatin. This is improper for at least the reason that a trademark merely designates the source of goods (i.e., the UPJOHN Company) and does not, as a matter of law, designate any characteristics of the goods themselves. For example, a company may change the composition of a product from time-to-time but still market the product under a common trademark. Moreover, the Examiner relies on a U.S. trademark registration, whereas the Kelly reference is authored by researchers in Cambridge, England and the source of the alleged Gelfoam is said to be McDonald & Company of Leicestershire, England. It is not seen that the mere reference to “Gelfoam” in this context would imply a particular material, based on a U.S. trademark registration. Moreover, a trademark registration, particularly under these circumstances, cannot serve to establish an inherent property of Kelly’s swabs, particularly where the reference is plainly contradictory to this position. Furthermore, one skilled in the art would not be led to use gelatin based on the Gelfoam reference in Kelly, because the mere mention of this mark would not have compelled the conclusion that the description of the swab as polyester was erroneous. To the contrary, Applicants submit that one skilled in the art would attach far more importance to a scientific description such as “polyester” than on a trademark.

Moreover, no matter what material Kelly actually employed, Kelly teaches that it has no advantages over a cottonwool swab. Kelly describes using either a “standard cottonwool variety” swab or a “polyester foam swab” for the purpose of comparing the efficacy of each type of swab. See Kelly, p. 81, left column, lines 10-12; p. 82, left column, lines 23-25. Kelly concludes that “[a] polyester foam swab was shown to have **no advantage** over the standard cottonwool variety.” (Abstract). Accordingly, regardless of the nature of Kelly’s sponge, one skilled in the art would not be led to develop a device for “for sampling and recovering a target” using a polyester or gelatin foam sponge because Kelly recognizes none of the advantages of a gelatin sponge identified in the present application.

For all of the foregoing reasons, Applicants respectfully request withdrawal of the rejection based on Kelly because any combination of references that includes Kelly fails to teach or suggest all of the required elements of the claims. Having distinguished the independent claims from the art of record, Applicants submit that the dependent claims are patentable for at least the same reasons. However, Applicants reserve the right to separately address the patentability of those claims in the future, should that become necessary.

Comments on Reasons for Allowability

Applicants thank the Examiner for indicating that claims 95, 141, and 158 are allowable. However, Applicants respectfully traverse the Office Action's summary of Berthold (U.S. Patent No. 6,218,176), and Applicants reserve the right to separately address Berthold should that become necessary. Briefly, the Examiner's contention that Berthold discloses the step of swiping a pre-wetted swab and a dry swab over the same surface is not correct. Rather, Berthold provides a sampling device with a handle and an absorbent tip to obtain a sample from a surface (Col. 5, lines 58-65), which may comprise dried luciferase (Col. 6, lines 18-20). It is the surface, and not the swab that is pre-wetted. In the method suggested by Berthold, one to three drops of a solution are applied to the test surface, and the absorbent tip is then wiped across the solution on the test surface to obtain a sample. The device is then placed in a tube (Col. 6., lines 5-17 and Example 1, 2). It is explicitly cited that "one sampling device is used at a time" (Col 6, line 59). The control swab used in Example 1 is just that; a control swab without luciferase that is tested under identical conditions as the luciferase-swab. However, the luciferase-swab and the control swab are not used successively. Nevertheless, Applicants thanks the Examiner for the acknowledgement that claims 95, 141, and 158 define patentable subject matter.

CONCLUSION

Applicants respectfully submit that the instant application is in condition for allowance. Entry of the amendments and an action passing this case to issue is therefore respectfully requested. In the event that a telephone conference would facilitate examination of this application in any way, the Examiner is invited to contact the undersigned at the number provided.

AUTHORIZATION


The Commissioner is hereby authorized to charge any fees which may be required for this amendment, or credit any overpayment to Deposit Account No. 50-3732, Order No. 13323.105003. Furthermore, in the event that an extension of time is required, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to the above-noted Deposit Account No. 50-3732 and Order No. 13323.105003.

Respectfully submitted,

KING & SPALDING, L.L.P.

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By:


Jonathan D. Ball
Registration No. 59,928

Mailing Address:

KING & SPALDING, L.L.P.
1185 Avenue of the Americas
New York, New York 10036-4003
(212) 556-2115
(212) 556-2222 (Fax)